

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

In re patent application of: BOUQUET, et al  
 Serial No.: 09/892,612  
 Filed: June 28, 2001  
 For: IMMORTALIZED AVIAN CELL LINES

Examiner: Zeman, Robert A.  
 Art Unit: 1645  
 Docket #: P06152US01/BAS

COMMISSIONER FOR PATENTS  
 WASHINGTON, D.C. 20231  
 SIR:

Attached is:

- ..... a response after Final Rejection dated
- ☒ a response to the Office Action dated October 2, 2002 with Attachments A-D
- ..... a Preliminary Amendment
- ☒ a Petition for an extension of time
- ☒ Other: Two Terminal Disclaimers (U.S. Patents Nos. 6,280,970 and 6,255,108)

Fees: For claims if required and/or other fees as shown below:

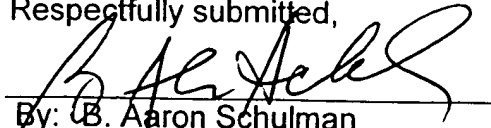
	NOW	Previously Paid For	Present Extra	Rate	\$
..... TOTAL CLAIMS	9	20		X \$ 18 =	
..... INDEP. CLAIMS	1	3		X \$ 84 =	
TOTAL OF ABOVE CLAIMS FEES =					
..... Reduction by ½ for <b>small entity status</b> of applicant					
SUBTOTAL =					
<input checked="" type="checkbox"/> Fee for extension of time (per attached Petition)					110
<input checked="" type="checkbox"/> Other fee for two (2) Terminal Disclaimers (\$110 x2)					220
TOTAL OF ALL FEES =					<b>330</b>

☒ A check in the amount of \$330 is enclosed. If no check or an insufficient check is enclosed and a fee is due in connection herewith, the Commissioner is authorized to charge any fee or additional fee due in connection herewith to Deposit Account No. 12-0555.

☒ In the event that a petition for extension of time is required to be submitted herewith and that a separate petition is not submitted herewith, applicant hereby petitions under 37 CFR 1.136(a) for an extension of time of as many months as are required to render this submission timely. Any fee is authorized above.

Respectfully submitted,

Date: February 3, 2003

By:   
 B. Aaron Schulman  
 Registration No.: 31877

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B/S



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UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,612	06/28/2001	Jean-Francois Bouquet	P06152US01/BAS	5691

881 7590 10/02/2002

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ALEXANDRIA, VA 22314

EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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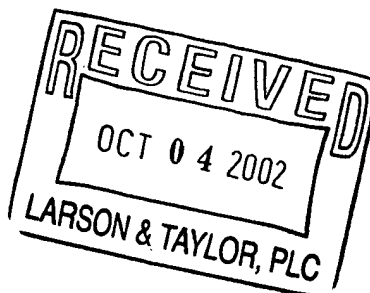
1645

DATE MAILED: 10/02/2002

3

1-2-03

Please find below and/or attached an Office communication concerning this application or proceeding.



**Office Action Summary**

Application No.

09/892,612

Applicant(s)

BOUQUET ET AL.

Examiner

Robert A Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/194,020.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-9 are pending and currently under examination.

#### ***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Additionally, it is unclear why the instant application was filed as a divisional of Application No. 09/194,020 since said application was never subjected to a restriction requirement.

#### ***Specification***

The brief description of the Drawings on page 6 should be labeled as such. Additionally, there is no differentiation between the "LTR" and the "Deleted LTR" in the description of the drawings. It is suggested that the designation "LTR" on line 3 be amended to LTR to correspond to the terminology used in Figure 1.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that cell line TDF-2A is required in order to practice the claimed invention. The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention {see 37 CFR 1.808(a)}. The Examiner acknowledges the deposit of organisms under Pasteur Institute National Collection of Microorganism Cultures (CNCM) accession number I-1712 in partial compliance with this requirement. However, the deposits are not in full compliance with 37 CFR 1.803-1.809.

If a deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements.

See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, should be submitted stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- 1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- 2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
- 3) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- 4) a viability statement in accordance with the provisions of 37 CFR 1.807; and

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5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,280,970. Although the conflicting claims are not identical, they are not patentably distinct from each other because said claims are all drawn to methods of producing viruses using an avian cell line comprising avian embryonic fibroblast cells which are immortalized but untransformed, the cells comprising, integrated into their genome, the SV 40 T + t gene. Said cell lines include the TDF-2A cell line.

Claims 1-5 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,255,108. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because said claims are all drawn to methods of producing viruses using an avian cell line comprising avian embryonic fibroblast cells which are immortalized but untransformed, the cells comprising, integrated into their genome, the SV 40 T + t gene. Said cell lines are fully encompassed by the avian cells that are immortalized but untransformed as disclosed in U.S. Patent 6,255,108.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: those required for the propagation of viruses utilizing avian cell lines comprising avian cells which are immortalized but untransformed, the cells comprising, integrated into their genome, an anti-apoptotic bcl-2 gene. The instant claims merely recite limitations regarding the cell lines and viruses used but are totally remiss in reciting any active steps that need to be performed.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the phrase "on an avian cell line". It is unclear what is meant by said term. Is Applicant stating that the viruses are produced on the

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extracellular portion of the cell membrane? Is viral infection required? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 1 is rendered vague and indefinite by the use of the phrase “comprising avian embryonic fibroblast cells...”. It is unclear what is meant by said phrase. Is the term “comprising” applicable to the avian cell line or the method for producing virus? As written, it is impossible to determine the metes and bounds of the claimed invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Diseases, 1984, Vol. 28 No. 1, pages 168-178).

Claim 9 recites a product by process. The MPEP discusses product-by -process claims in chapter 2100: “Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process.” See MPEP 2113.



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The cited art sets forth Adenovirus 127 as being a virus that infects birds (avians) and appears to be the same virus disclosed by Applicant in Example 3. Whether the virus disclosed by Brugh et al. and that resulting from the claimed process are the same, is not clear, and the Office does not have the facilities to perform such comparative analyses. In a discussion of product-by-process claims, this court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by-process claims in *In re Best*: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). Since the instant claim reads on any virus, the disclosure by Brugh et al. anticipates the limitations of the rejected claim.

### ***Conclusion***


No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
DONNA WORTMAN  
PRIMARY EXAMINER

Robert A. Zeman  
September 30, 2002

<b>Notice of References Cited</b>	Application/Control No. 09/892,612	Applicant(s)/Patent Under Reexamination BOUQUET ET AL.	
	Examiner Robert A Zeman	Art Unit 1645	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,255,108	07-2001	Bouquet et al.	
	B	US-6,280,970	08-2001	Bouquet et al.	
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Brugh et al. Avian Diseases, 1984, Vol. 28 No. 1, pages 168-178.
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



Form PTO-1449

Docket No. XI/P06152US0

Serial No. 09/194 020

INFORMATION DISCLOSURE  
CITATION IN AN  
APPLICATION

Applicant: BOUQUET et al

09/892,612

Filing Date: 12/22/98  
6/28/01Group Art Unit:  
assigned

## U.S. PATENT DOCUMENTS

Ex. In.	Document No.	Date	Name	Class	Subclass	Filing Date

## FOREIGN PATENT DOCUMENTS

Ex. In.	Document No.	Date	Country	Class	Subclass	Trans. Y/N
RZ	RZ	0 242 272 A1	10/21/87	EPO (in French)		~
RZ	RZ	WO 92/10563	6/25/92	WIPO (in French with English abstract)		~
RZ	RZ	WO 93/20200	10/14/93	WIPO		
RZ	RZ	WO 91/18971	12/12/91	WIPO		

## OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

RZ	RZ	"The 12S adenoviral E1A protein immortalizes avian cells and interacts with the avian RB product", Guilhot et al, <i>Oncogene</i> , 1993, Vol. 8, pages 619-624
RZ	RZ	"Human membrane cofactor protein (CD46) acts as a cellular receptor for measles virus", Naniche et al, <i>Journal of Virology</i> , October 1993, pages 6025-6032
RZ	RZ	"Immortalization of human fibroblasts transformed by origin-defective simian virus 40", Neufeld et al, <i>Molecular and Cellular Biology</i> , August 1987, pages 2794-2802
RZ	RZ	"Overexpression of human cyclin A advances entry into S phase", Rosenberg et al, <i>Oncogene</i> 1995, Volume 10, pages 1501-1509
RZ	RZ	"Activation of Epstein-Barr virus-latent genes protects human B-cells from death by apoptosis", Gregory et al, <i>Nature</i> , Feb. 2, 1991, Vol. 349, pages 612-614

Examiner

Date Considered

12/6/99

Examiner: Initial if considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

9/24/02

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Form PTO-1449  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>	Docket No. XI/P06152US0	Serial No. 09/194,020 <b>07/8925/2</b>
	Applicant: BOUQUET et al	
	Filing Date: 12/22/98	Group Art Unit: Not assigned

## U.S. PATENT DOCUMENTS

Ex. In.	Document No.	Date	Name	Class	Subclass	Filing Date

## FOREIGN PATENT DOCUMENTS

Ex. In.	Document No.	Date	Country	Class	Subclass	Trans. Y/N
RZ	0 242 272 A1	10/21/87	EPO (in French)			~
RZ	WO 92/10563	6/25/92	WIPO (in French with English abstract)			~
RZ	WO 93/20200	10/14/93	WIPO			
RZ	WO 91/18971	12/12/91	WIPO			

## OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

RZ	"The 12S adenoviral E1A protein immortalizes avian cells and interacts with the avian RB product", Guilhot et al, <i>Oncogene</i> , 1993, Vol. 8, pages 619-624
RZ	"Human membrane cofactor protein (CD46) acts as a cellular receptor for measles virus", Naniche et al, <i>Journal of Virology</i> , October 1993, pages 6025-6032
RZ	"Immortalization of human fibroblasts transformed by origin-defective simian virus 40", Neufeld et al, <i>Molecular and Cellular Biology</i> , August 1987, pages 2794-2802
RZ	"Overexpression of human cyclin A advances entry into S phase", Rosenberg et al, <i>Oncogene</i> 1995, Volume 10, pages 1501-1509
RZ	"Activation of Epstein-Barr virus-latent genes protects human-B cells from death by apoptosis", Gregory et al, <i>Nature</i> , Feb. 2, 1991, Vol. 349, pages 612-614

Examiner

*Robert Z...*

Date Considered

*12/6/99*

Examiner: Initial if considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.